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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,909	12/18/2001	Heather L. Davis	C1039/7058(HCL X04/19/02)	8458

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EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/023,909	Applicant(s) DAVIS ET AL.	
	Examiner J. Parkin	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *01* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2003* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Restriction Requirement

35 U.S.C. § 121

1. Acknowledgement is hereby made of receipt and entry of the communication filed 05 May, 2003. Applicants are hereby advised that the restriction requirement set forth in paper no. 6 is hereby vacated in view of the following requirement. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

a. Group I, claims 1-3, 8-14, 20-34, drawn to a **method of inducing an antigen-specific immune response** through the administration of a composition comprising a **depo effect-inducing adjuvant** (e.g., alum) and a **CpG dinucleotide-based adjuvant**, classified in class 424, subclass 278.1, class 536, subclass 23.1, and class 514, subclass 44.

b. Group II, claims 1, 4, 5, 8-14, 20-33, and 35, drawn to a **method of inducing an antigen-specific immune response** through the administration of a composition comprising an **immune stimulating adjuvant** (e.g., MPL) and a **CpG dinucleotide-based adjuvant**, classified in class 424, subclass 278.1, class 536, subclass 23.1, and class 514, subclass 44.

c. Group III, claims 1, 6-14, and 20-33, drawn to a **method of inducing an antigen-specific immune response** through the administration of a composition comprising a **depo effect-inducing/immune stimulating adjuvant** (e.g., ISCOMs) and a **CpG dinucleotide-based adjuvant**, classified in class 424, subclass 278.1, class 536, subclass 23.1, and class 514, subclass 44.

d. Group IV, claims 1-3 and 8-34, drawn to a **method of inducing an antigen-specific immune response** through the administration of a composition comprising a **depo effect-inducing adjuvant** (e.g., alum) and a **modified CpG dinucleotide-based adjuvant**, classified in class 424, subclass 278.1, class 536, subclass 23.1, and class 514, subclass 48.

e. Group V, claims 1, 4, 5, 8-33, and 35, drawn to a **method of inducing an antigen-specific immune response** through the administration of a composition comprising an **immune stimulating adjuvant** (e.g., MPL) and a **modified CpG dinucleotide-based adjuvant** , classified in class 424, subclass 278.1, class 536, subclass 23.1, and class 514, subclass 48.

f. Group VI, claims 1 and 6-33, drawn to a **method of inducing an antigen-specific immune response** through the administration of a composition comprising a **depo effect-inducing/immune stimulating**

adjuvant (e.g., ISCOMs) and a **modified CpG dinucleotide-based adjuvant**, classified in class 424, subclass 278.1, class 536, subclass 23.1, and class 514, subclass 48.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I-VI are each unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified groups employs structurally and functionally disparate compositions (e.g., depo effect-inducing adjuvants such as alum, immune stimulating adjuvants such as MPL, dual acting adjuvants such as ISCOMs, CpG dinucleotide-based adjuvants, and phosphorothioate-modified CpG dinucleotide-based adjuvants). Since each of the identified groups employs different compositions, separate searches will also be required. Accordingly, each of the identified groups is clearly directed toward an independent and distinct invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and require separate searches, restriction for examination purposes as indicated is proper.

4. Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143). **Applicants are also advised that the claims should be amended to reflect the election, where necessary.** If one of Groups IV-VI are selected, the claims should be amended to reflect the requirement for a **modified** CpG dinucleotide-containing adjuvant.

5. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(I).

Correspondence

6. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward the following Group 1600 fax number: (703) 872-9306. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (703) 308-1122 or (703) 308-4027, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

06 September, 2003